4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0229]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria. FDA has determined that XURIDEN (uridine triacetate), manufactured by Wellstat Therapeutics Corp., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Larry Bauer, Rare Diseases Program, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4842, FAX: 301-796-9858, larry.bauer@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

FDA is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of rare

pediatric disease product applications that meet certain criteria. FDA has determined that XURIDEN (uridine triacetate), manufactured by Wellstat Therapeutics Corp., meets the criteria for a priority review voucher. Uridine triacetate is a pyrimidine analog for uridine replacement. XURIDEN is indicated for the treatment of hereditary orotic aciduria. Hereditary orotic aciduria is caused by a deficiency in the activity of the pyrimidine pathway enzyme uridine 5'-monophosphate synthase. The disorder is generally characterized by anemia and/or other hematological manifestations, excessive urinary excretion of orotic acid, failure to thrive, and developmental delay.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.

For further information about XURIDEN (uridine triacetate), go to the Drugs@FDA Web site at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm.

Dated: September 24, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-24640 Filed: 9/28/2015 08:45 am; Publication Date: 9/29/2015]